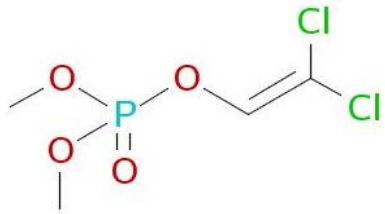
DICHLORVOS

This EQS dossier was prepared by the Sub-Group on Review of the Priority Substances List (under Working Group E of the Common Implementation Strategy for the Water Framework Directive).

The dossier was reviewed by the Scientific Committee on Health and Environmental Risks (SCHER), which commented on the use of an additional assessment factor for the marine EQS. Further explanation for that use is given in section 3.1. The SCHER also commented on the human health assessment and section 7.3 has been amended.

1 CHEMICAL IDENTITY

Common name	Dichlorvos
Chemical name (IUPAC)	Phosphoric acid, 2,2-dichloroethenyl dimethyl ester
Synonym(s)	DDVP
Chemical class (when available/relevant)	Organophoshorous insecticide and acaricide Inhibitor of acetylcholinesterase
CAS number	62-73-7
EU number	200-547-7
Molecular formula	$C_4H_7Cl_2O_4P$
Molecular structure	
Molecular weight ($g.mol^{-1}$)	221.0

2 EXISTING EVALUATIONS AND REGULATORY INFORMATION

Annex III EQS Dir. (2008/105/EC)	Not Included
Existing Substances Reg. (793/93/EC)	Not applicable
Pesticides(91/414/EEC)	Not included in Annex I - Commission Decision 2007/387/EC
Biocides (98/8/EC)	Included in the review programme as Product Type 18 - Insecticides
PBT substances	Not investigated
Substances of Very High Concern (1907/2006/EC)	No
POPs (Stockholm convention)	Not investigated
Other relevant chemical regulation (veterinary	No

products, medicament, ...)	
Endocrine disrupter	Deemed not to be endocrine disrupters, on the basis of available information (E.C., 2004) More precisely, according to Petersen *et al.*, 2007: - Human health: Cat. 3a (studies available but no indications of endocrine disrupter effects). - Wildlife: Cat. 3b (Substances with no or insufficient data gathered)

3 PROPOSED QUALITY STANDARDS (QS)

3.1 ENVIRONMENTAL QUALITY STANDARD (EQS)

$QS_{water, eco}$ for protection of aquatic organisms is the "critical QS" for derivation of an Environmental Quality Standard.

Data are available on 3 trophic levels for both acute and chronic ecotoxicity and an assessment factor of 10, respectively 100, is applied for derivation of QS_{water_eco}, respectively MAC-EQS. Significant differences between freshwater and marine species cannot be demonstrated from the information available, but data from additional marine taxonomic groups are not available that might have reduced the uncertainties associated with extrapolation to the marine ecosystem, i.e. with the greater species diversity in the marine environment and the possibly greater sensitivity of marine species and taxa not in the experimental dataset.

	Value	**Comments**
Proposed AA-EQS for [freshwater] [µg.L^{-1}]	**6 10^{-4}**	**Critical QS is $QS_{water, eco}$.**
Proposed AA-EQS for [marine water] [µg.L^{-1}]	**6 10^{-5}**	**See section 7**
Proposed MAC-EQS for [freshwater] [µg.L^{-1}]	**7 10^{-4}**	**See section 7.1**
Proposed MAC-EQS for [marine water] [µg.L^{-1}]	**7 10^{-5}**	

3.2 SPECIFIC QUALITY STANDARD (QS)

Protection objective*	**Unit**	**Value**	**Comments**
Pelagic community (freshwater)	[µg.l^{-1}]	5.8 10^{-4}	See section 7.1
Pelagic community (marine water)	[µg.l^{-1}]	5.8 10^{-5}	
Benthic community (freshwater)	[µg.kg^{-1} $_{dw}$]	2.1 10^{-3}	e.g. EqP, see section 7.1
Benthic community (marine)	[µg.kg^{-1} $_{dw}$]	2.1 10^{-4}	
Predators (secondary poisoning)	[µg.kg^{-1} $_{biota\ ww}$]	22	See section 7.2
	[µg.l^{-1}]	18 (freshwater) 18 (saltwater)	
Human health via consumption of fishery products	[µg.kg^{-1} $_{biota\ ww}$]	0.2	See section 7.3
	[µg.l^{-1}]	0.17 (freshwater) 0.17 (saltwater)	
Human health via consumption of water	[µg.l^{-1}]	0.1	

Quality standards for protection of benthic organisms are derived in section 7.1 and reported in the table above for information only as they are not taken into account in the derivation of the EQS (cf. section 7.1 and the TGD-EQS, E.C., 2011).

* Please note that as recommended in the Technical Guidance for deriving EQS (2011), "EQSs […] are not reported for 'transitional and marine waters', but either for freshwater or marine waters". If justified by substance properties or data available, QS for the different protection objectives are given independently for transitional waters or coastal and territorial waters.

ETOX database[†] refers to existing Quality Criteria (ETOX, 2007):

- United Kingdom: Proposed provisional EQS, PEQS, corresponding to $QS_{water, eco}$:
  - in freshwater = 0.001 µg.l^{-1}
  - In saltwater = 0.04 µg.l^{-1}
- Germany: Quality Criteria for:
  - the protection of aquatic life and freshwater, corresponding to $QS_{water, eco}$ = 6 10^{-4} µg.l^{-1}
  - for drinking water abstraction, corresponding to $QS_{dw, hh}$ = 0.1 µg.l^{-1}

[†] http://webetox.uba.de/webETOX/public/basics/ziel.do?id=3107

4 MAJOR USES AND ENVIRONMENTAL EMISSIONS

4.1 USES AND QUANTITIES

Dichlorvos is an organophosphorous insecticide.

Dichlorvos is included in the review programme of Directive 98/8/EC as Product Type 18 – Insecticides, and is still under review.

Dichlorvos has been used as plant protection products in greenhouses applications, and post-harvest application in stores. Dichlorvos is used for external protection against harmful organisms. Application is direct on organisms. Dichlorvos is not sprayed directly on the crops. Dichlorvos has not been included in Annex I to Directive 91/414/EC.

The information below is extracted from EU-DAR (E.C., 2005).

.5.3 Summary of intended uses (IIA 3.4; IIIA 3.3 to 3.7, 3.9)

.5.3.1 Details of existing and intended uses (IIA 3.4; IIIA 3.3)

Table 1 2 Details of existing and intended uses

Crop	Disease	Effect
Existing and Intended uses		insecticidal; knock down of insects
starting material	aphid, thrips and whitefly	
flowering crops	aphid, thrips and whitefly	
ornamental plants and trees	aphid, thrips and whitefly	
stored flower bulbs	thrips	
cereals in store	insects (beetles, weevils etc.)	
Other existing uses		
cucumbers in greenhouses	thrips	
stored products: nuts, almonds, cacao etc.)	beetles, moths	

Table 1 3 Summary of uses supported by available data (active substance) July 2003

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Flower-bulbs		Dichlorvos 550 g/L EC	I	Thrips	EC	550 g/L	Room treatment	N.A.	Max: 3	2 days	2.2 kg/hL	45 L/ha	2.2 g/100 m^3	N.A.	Application rate based on an average height of 4.5 m for a storage

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

4.2 ESTIMATED ENVIRONMENTAL EMISSIONS

There is no information available on environmental emissions.

5 ENVIRONMENTAL BEHAVIOUR

5.1 ENVIRONMENTAL DISTRIBUTION

		Master reference
Water solubility (mg.l^{-1})	18 000	EFSA, 2006
Volatilisation	**Volatilisation is a major route of dissipation of the substance from water phase.**	
Vapour pressure (Pa)	2.1 at 25°C	EFSA, 2006
Henry's Law constant (Pa.m^3.mol^{-1})	0.026 at 25°C	EFSA, 2006
Adsorption	**The value 37 is used for derivation of QS.**	
Organic carbon – water partition coefficient (K_{OC})	K_{OC} = 37	US-EPA, 2005
Sediment – water partition coefficient($K_{sed-water}$)	$K_{sed-water}$ = 1.73	*Calculated from K_{OC}*
Bioaccumulation	**The BCF value 1.2 on fish is used for derivation of QS. Thus, BMF_1 = BMF_2 = 1** (E.C., 2011)**.**	
Octanol-water partition coefficient (Log Kow)	1.9 at 25°C	EFSA, 2006
BCF (measured)	1.2	E.C., 2005a

5.2 ABIOTIC AND BIOTIC DEGRADATIONS

		Master reference
Hydrolysis	**At 20°C:** **DT_{50}= 31h, at pH 7** DT_{50}= 0.013h, at pH 13 At 30°C: DT_{50}= 74h at pH 1 DT_{50}= 18h at pH 7 DT_{50}= 50h at pH 5 DT_{50}= 16h at pH 9	E.C., 2005a
Photolysis	Not relevant. No studies available.	E.C., 2005a
Biodegradation	*In an acceptable OECD guideline ready biodegradability study (E.C., 2005b) that utilised a sewage sludge innoculum, dichlorvos was classified as 'readily biodegradable' based on a test concentration of 2mg/L but 'not readily biodegradable' based on a test concentration of 5mg/L. Member state experts considered that as a result of this study, for classification purposes dichlorvos should be considered 'not readily biodegradable'.*	EFSA, 2006

6 AQUATIC ENVIRONMENTAL CONCENTRATIONS

6.1 ESTIMATED CONCENTRATIONS

Compartment	Predicted environmental concentration (PEC)	Master reference
Freshwater	No data available	Daginnus *et al.*, 2009[(1)]
Marine waters (coastal and/or transitional)	No data available	Daginnus *et al.*, 2009[(1)]
Sediment	No data available	Daginnus *et al.*, 2009[(1)]
Biota (freshwater)	No data available	Daginnus *et al.*, 2009[(1)]
Biota (marine)	No data available	Daginnus *et al.*, 2009[(1)]
Biota (marine predators)	No data available	Daginnus *et al.*, 2009[(1)]

[(1)] *data originated from EU modelling-based prioritisation results.*

6.2 MEASURED CONCENTRATIONS

Compartment		Measured environmental concentration (MEC)	Master reference
Freshwater (µg/l)		PEC 1: $2.55.10^{-2}$	James *et al.*, 2009[(1)]
Marine waters (coastal and/or transitional) (µg/l)		PEC 2: $2.04.10^{-2}$	James *et al.*, 2009[(1)]
WWTP effluent (µg/l)		No data available	
Sediment (µg/kg dw)	Sed 2 mm	PEC 1: - PEC 2: 25	James *et al.*, 2009[(1)]
	Sed 20 µm	No data (*0*)	
	Sed 63µm	No data (*0*)	
Biota	Invertebrates (µg/kg ww)	No data (*0*)	James *et al.*, 2009[(1)]
	Fish (µg/kg ww)	No data (*0*)	
	Marine predators	No data available	

7 EFFECTS AND QUALITY STANDARDS

7.1 ACUTE AND CHRONIC AQUATIC ECOTOXICITY

All data presented extracted from EU-DAR (E.C., 2005a) thereafter are considered as peer-reviewed. In Annex B.9.2 of the DAR the following remark is made:

«In all studies on aquatic organisms the concentration verification was not provided and the only information available was the nominal concentration. Therefore it is not possible to decide whether the toxicity should be expressed as initial measured concentration or nominal concentration. For this reason all studies are not acceptable. However, for a preliminary risk assessment, end points expressed as nominal concentration have been taken into account. »

Algae and fish data from the DAR are not exhaustively reported. The DAR reports a number of additional data on fish hand also reports results of a review on fish toxicity data from the open literature that was submitted to the German BBA.

The data extracted from US-EPA Pesticide Ecotoxicity Database (US-EPA, 2009) are considered valid or valid with restriction when they were categorized as “Core data” and “Supplemental data” (see note). A large number of references is available in the EPA ecotox database alone contains over 1000 entries): none of them however is lower than the chronic data reported in the following table.

ACUTE EFFECTS			**Reliability**	**Master reference**
Algae & aquatic plants ($mg.l^{-1}$)	**Freshwater**	*Selenastrum capricornutum* / 94 h EC_{50} : 140	Static test, no verification of test concentrations.	E.C., 2005a
	Marine	No available information		
Invertebrates ($mg.l^{-1}$)	**Freshwater**	***Daphnia pulex* / 48h** **EC_{50}: 7 10^{-5}**	*Core* (1)	E.C., 2005a US-EPA, 2006
		Daphnia magna / 48h EC_{50} = 1.9 10^{-4}	no verification of test concentrations	E.C., 2005a
	Marine	*Americamysis bahia* / 96 h LC_{50} : 0.019	4 *Core* (1)	US-EPA, 2006
	Sediment	*Chironomus riparus* / 24h EC_{50} = 0.017	no verification of test concentrations	E.C., 2005a
Fish ($mg.l^{-1}$)	**Freshwater**	*Oncorhynchus mykiss* / 96h LC_{50} = 0.55	1	EFSA, 2006
		Pimephales promelas / 96h LC_{50} = 3.72	1	EFSA, 2006
		Salvelinus namaycush / 96h LC_{50} : 0.18 – 0.19	4 *Supplemental* (1)	US-EPA, 2006
		Lepomis macrochirus / 96h LC_{50} : 0.869	4 *Core* (1)	US-EPA, 2006
		Lepomis macrochirus / 96h LC50 0.27 (soft water) LC50 0.35 (hard water)	2	EFSA, 2006
	Marine	*Cyprinodon variegatus* / 96 h LC_{50} : 6.1	4 *Core* (1)	US-EPA, 2006
	Sediment	No available information		
Other taxonomic groups		No available information		

CHRONIC EFFECTS			Reliability	Master reference
Algae & aquatic plants ($mg.l^{-1}$)	**Freshwater**	*Scenedesmus subspicatus* / 96h NOEC = 18	no verification of test concentrations	Crommentuijn *et al.*, 1997
	Marine	No available information		
	Freshwater	*Daphnia magna* / 21 d NOEC : 1.6 10^{-7} (0.16 ng/L)	3 (1)	E.C., 2005a
		***Daphnia magna* / 21 d** **$NOEC_{reproduction}$: 6.0 10^{-6}** (6 ng/L)	2	Bruns and Knacker, 1998
		Daphnia magna / 21 d NOEC : 5.8 10^{-6} (5.8 ng/L)	4 *Core* (1)	US-EPA, 2006
	Marine	*Americamysis bahia* / 28 d NOEC : 0.0015	*Core* (1)	US-EPA, 2006
	Sediment	No available information		
Fish ($mg.l^{-1}$)	**Freshwater**	*Oncorhynchus mykiss* / 61 d NOEC : 5.2 10^{-3}	*Core* (1)	US-EPA, 2006; US-EPA, 2009
	Marine	*Cyprinodon variegatus* / 34 d NOEC : 0.96	*Core* (1)	US-EPA, 2006

(1) The three study categories used by the US-EPA to classify studies are core, supplemental, and invalid. Classification as "Core" data means that all essential information was reported and the study was performed according to recommended EPA or ASTM methodology. "Supplemental" studies are scientifically sound; however, they were performed under conditions that deviated substantially from recommended protocols. Results do not meet guideline requirements; however, the information may be useful in a risk assessment. For more details, please see http://www.ipmcenters.org/Ecotox/DatabaseGuidance.pdf.

The lowest results were obtained with the invertebrate *Daphnia magna* for which 3 results are available.

The lowest one is considered as not acceptable according to EFSA (E.C., 2005a) because analytical measurement of the substance in the media was not realized while the substance is readily biodegradable.

The International Commission for the Rhine protection proposes to use the $NOEC_{reproduction}$ of 6.0 10^{-6} mg/l on *Daphnia magna* to determine an aquatic quality standard with an assessment factor of 10[‡] (Bruns and Knacker, 1998), The NOEC is based on effects on reproduction. The concentrations were measured. From the original reference it appears that there were problems with analytical verification of test concentrations; recovery was acceptable at 0.063 and 0.2 µg/L, but at lower nominal concentrations, actual measured exhibited a high variability. (In the report lower concentrations are denoted as < 0.02 mg/L, but this should most likely read 0.02 **µ**g/L). In each concentration level, the test substance was renewed three times per week during the period of the test. The authors recognize the deficiencies concerning the analytical method used, and provide the following argumentation: the variability in freshly prepared sample is similar to 48h aged samples; the variability is correlated with decreasing concentrations, dichlorvos was detected in control samples, although no effects were detected in control, thus leading to the conclusion that the analytical method was not appropriate. The authors conclude that since the stock solution concentrations and the highest test concentrations were analytically verified, that there is no indication of mistake when preparing the solution and that the biological data shows a clear dose-response relationship, it is assume that the nominal concentrations can be used. The semi-statics conditions are also in favour of an acceptable control of the exposure conditions.

[‡] http://www.iksr.org/fileadmin/user_upload/Dokumente_de/Berichte/Bericht__Nr._164.pdf

An additional study is reported by US-EPA, 2006 as a core study but was not available for review. This study is a flow-through study; it is not known however whether the result is based on nominal or measured concentrations. Results are however very similar to those observed in the study from Bruns and Knacker, 1998. It is recommended when several studies are available for the same endpoint and the same species to use the geometric mean.

For the purpose of QS determination, the value of 6.10^{-3} µg.l^{-1} is proposed.

It must be noted that Dichlorvos is currently under evaluation in the review programme for existing biocidal substances.

The following QS is proposed, but may need to be revised when the results of the new test become available.

Tentative QS_{water}	**Relevant study for derivation of QS**	**Assessment factor**	**Tentative QS**
$MAC_{freshwater, eco}$	*Daphnia pulex* / 48h	100	7 10^{-4} µg.l^{-1}
$MAC_{marine\ water, eco}$	EC_{50} : 7 10^{-2} µg.l^{-1}	1000	7 10^{-5} µg.l^{-1}
$AA\text{-}QS_{freshwater, eco}$	*Daphnia magna* / 21 d	10	6 10^{-4} µg.l^{-1}
$AA\text{-}QS_{marine\ water, eco}$	NOEC : 6 10^{-3} µg.l^{-1}	100	6 10^{-5} µg.l^{-1}
$AA\text{-}QS_{freshwater, sed.}$	-	EqP	7.9 10^{-4} µg.kg$^{-1}_{ww}$ 2.1 10^{-3} µg.kg$^{-1}_{dw}$
$AA\text{-}QS_{marine\ water, sed.}$	-	EqP	7.9$10^{-5}$ µg.kg$^{-1}_{ww}$ 2.1 10^{-4} µg.kg$^{-1}_{dw}$

7.2 SECONDARY POISONING

In the Technical Guidance Document on EQS derivation,it is recommended to derive a $QS_{biota\ sec\ pois}$ in either of the 4 cases

- *the substance is measured BMF>1 or BCF (BAF) ≥100*
- *no valid measured BMF or BCF (BAF) is available, but Log Kow ≥ 3*
- *there is other evidence of bioaccumulation potential (e.g. biota monitoring data, structural alerts) PROVIDED THAT there is no mitigating property such as rapid degradation (ready biodegradability or hydrolysis half-life <12h at pH 5-9, 20°C) or obvious molecular size exclusion*
- *the substance has high intrinsic toxicity to mammals and birds (except carcinogenicity)*

Given the oral toxicity data available (see below), $QS_{biota\ sec\ pois}$ and $QS_{biota,\ hh}$ should therefore be derived.

Secondary poisoning of top predators		**Master reference**
Mammalian oral toxicity	Beagle dog (4/sex/dose)/ dietary /1 year/ cholinesterase inhibition 0 - 0,05 – 1 – 3 mg.kg^{-1} NOAEL = 0.05 mg.kg$^{-1}_{bw}$.d^{-1} NOEC = 2 mg.kg$^{-1}_{feed\ ww}$ (CF= 40)	AMVAC Chemical Corporation, 1990 *in* ATSDR, 1997
Avian oral toxicity	*Anas platyrhynchos* /oral / 20 weeks NOEC = 5 mg.kg$^{-1}_{feed\ ww}$	US-EPA, 2005

Tentative QS_{biota}	**Relevant study for derivation of QS**	**Assessment factor**	**Tentative QS**

Biota	NOEC = 2 $mg.kg^{-1}_{feed\ ww}$	90[(1)]	22.2 $\mu g.kg^{-1}_{biota\ ww}$ corresponding to 18.5 $\mu g.l^{-1}$ (freshwater) 18.5 $\mu g.l^{-1}$ (saltwaters)

(1) proposal made for the purpose of this dossier, according to REACH guidance on information requirements and chemical safety assessment (ECHA, 2008) and estimating the study to be "sub-chronic".

7.3 HUMAN HEALTH

Human health via consumption of fishery products		**Master reference**
Mammalian oral toxicity	Mouse and rat / gavage / 2 years / tumors Sf = 0,29 $(mg.kg^{-1}.d^{-1})^{-1}$ Virtually safe dose for a 10^{-6} risk = $3.5\ 10^{-6}$ $mg.kg^{-1}$	NTP, 1986a NTP, 1986b *in* US-EPA, 1994
	Beagle dog (4/sex/dose)/ dietary /1 year/ cholinesterase inhibition 0 - 0,05 – 1 – 3 $mg.kg^{-1}$ NOAEL = 0.05 $mg.kg^{-1}_{bw}.d^{-1}$	AMVAC Chemical Corporation, 1990 *in* ATSDR, 1997
	Dog / dietary / 2 years / cholinesterase inhibition LOAEL = 0.08 $mg.kg^{-1}_{bw}.d^{-1}$ NOAEL = 0.008 $mg.kg^{-1}_{bw}.d^{-1}$ Tentative ADI = 0.00008 mg/kg bw/day	EFSA, 2006
CMR	IARC: dichlorvos classified as in Group 2b (possibly carcinogenic to humans).	IARC, 2009

EFSA reviewed the substance in 2006 and stipulated that the results for carcinogenicity were inconclusive (Positive 2 out of 11 studies evidence of pancreatic adenomas and leukemia), noting that the quality of the studies was generally low (EFSA, 2006). EFSA analyzed that only forestomach carcinomas in mice could be attributed to an exposure to dichlorvos and proposed that a threshold could be considered for this effect (forestomach carcinomas). EFSA set a tentative ADI of 0.00008 mg/kg bw/day but recognized that the mode of action is not identified, and that the substance is genotoxic.

According to IARC carcinogenic classification, dichlorvos is possibly carcinogenic to humans.

It should be noticed that leukaemia, pancreatic tumors in rats are also reported within international literature.

The virtually safe dose determined in the non-threshold approach used for carcinogenic effects of dichlorvos has been used below in order to conservatively calculate the $QS_{biota,\ hh}$. The result indicates that, even using the conservative value, $QS_{biota,\ hh}$ is well above the quality standards calculated for aquatic organisms and the $QS_{biota,\ hh}$ is not likely to be the driving QS.

Tentative $QS_{biota\ hh}$	**Relevant data for derivation of QS**	**AF**	**Threshold Level**	**Tentative QSbiota, hh**
Human health	$3.5\ 10^{-6}$ $mg.kg^{-1}$	Not applicable	$3.5\ 10^{-6}$*(1)* $mg.kg^{-1}_{bw}.d^{-1}$	0.213 $\mu g.kg^{-1}_{bw}.d^{-1}$ corresponding to 0.178 $\mu g.l^{-1}$ (freshw.) 0.178 $\mu g.l^{-1}$ (saltw.)

(1) This value is considered valid as it was determined by E.C., 2006; US-EPA, 1994.

Human health via consumption of drinking water		**Master reference**
Existing drinking water standard(s)	0.1 $\mu g.l^{-1}$ (preferred regulatory standard)	Directive 98/83/EC

According to TGD-EQS (E.C., 2011) quality standards for protection of human health via consumption of drinking water are not calculated when a regulatory standard already exists (Directive 98/83/EC).

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